



American Bakers Association

Serving the Baking Industry Since 1897

August 30, 2002

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. 02N-0276; Solicitation for Comments, Section 305,
Registration of Food Facilities
PL107-188 (July 17, 2002)

Dear Sir/Madam:

These comments are submitted on behalf of the members of the American Bakers Association (ABA), the national trade association representing the wholesale baking industry. ABA membership consists of bakers and bakery suppliers who together are responsible for the manufacture of approximately 80 percent of the baked goods sold in the United States. The purpose of these comments is to provide information to FDA regarding registration of food facilities, specifically bakery facilities, under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (PL 107-188) as the agency proceeds to develop a proposed rule on this issue.

ABA welcomes the opportunity to provide information to assist the agency in developing a practical and applicable approach for registering bakery facilities. As ABA understands it, the purpose of the food facility registration is to authorize the Secretary of Health and Human Services to compile an up-to-date list of relevant facilities to enable him to rapidly identify and contact potentially affected facilities in the context of an investigation of bioterrorism involving the food supply. Below, ABA provides comments in specific issue areas where FDA has sought industry input.

Who Must Register

ABA believes that establishment of a flexible definition of "entity" is needed to allow companies to register as best suits their corporate structure. This would provide for the inclusion of one parent corporation to register all of its subsidiaries and plants through a single registration. This centralized approach would assist both the agency and companies to quickly and effectively pinpoint facilities in question.

02N-0276

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What Format and Procedures are to be Followed for Registration?

ABA thinks that the only practical and achievable way to implement registration of all food facilities is through electronic submission. In this task, it is important that the agency can provide confidentiality and assure authenticity for its documentation system. FDA should not prescribe to a specific (fill-in-the-blank) format. Requirements of the Act include names and addresses of each facility at which, and all trade names under which, the registrant conducts business. Individual companies should have the flexibility to provide the required information as best applies to its organization. FDA should confirm that under the regulatory language, it is not required to have separate registration for each facility but use a centralized registration as described above. FDA should take no longer than 30 days to assign a registration number after receipt of a registration. With regards to notification of changes, companies should report to FDA within sixty days.

What is the Content of the Registration?

ABA believes that FDA should include regulatory language that states that corporate offices of registrants being used for centralized registration should be identified along with a contact name. This centralized approach could greatly assist FDA in expediting the agency's and company's ability to expeditiously address issues of concern. Additionally, FDA should include regulatory language regarding the exemptions as defined by the congressional legislative history that exempts retail food establishments including grocery stores, convenience stores, cafeterias, lunch rooms, food stands, saloons, taverns, bars, lounges, catering and vending facilities or other similar establishments that store, prepare, serve or otherwise provide food directly to a retail consumer. Further, the term "facility" should not include trucks or other motor carriers used in the usual course of business as carriers.

Additionally, ABA does not believe that food categories are a necessary part of the registration information. Requiring this information does not achieve the intended purpose as outlined in the congressional language of Public Law 107-188. Detailed food categories could lead to burdensome and repetitive requests for changes to registrations as facilities add or remove food categories in their operation. Changes in production, product lines, packaging and even establishment names and brands change regularly. FDA should clarify what constitutes a "change" and should designate a reasonable and appropriate notification period, such as six months. It may also be helpful to clarify that a "change" would not require a new registration process or number.

American Bakers Association
Docket No. 02N-0276
August 30, 2002
Page 3

What is the effective date?

ABA believes that congressional oversight may be appropriate to assure that FDA meets the deadline to publish its final rule before December 12, 2003. This would allow industry sufficient time to prepare registrations. If regulations are not made effective by that date, companies would be required to register in any event, but would then need to amend registrations to comply with a final rule when it becomes effective. It is critical that FDA be prepared internally with necessary administrative resources and information management systems in place when the regulations go into effect or the default conditions will apply.

ABA appreciates this opportunity to comment on FDA's request for information regarding food plant registration as it applies to Public Law 107-188. This issue is of great interest to the wholesale baking industry. The technical contact for these comments is Lee Sanders, ABA Vice President, Regulatory and Technical Services, American Bakers Association, 1350 I Street, N.W., Suite 1290 Washington, D.C. 20005-3305 (telephone) 202-789-0300, (fax) 202-898-1164.

Respectfully submitted,

A handwritten signature in black ink, reading "Paul C. Abenante". The signature is fluid and cursive, with the first name "Paul" being more prominent.

Paul C. Abenante
President & CEO
American Bakers Association